

SAFETY DATA SHEET

according to Regulation (EU) 2015/830

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VERSION: 1.0

1. SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name	Cerec Optispray 200ml
Product code	6317932
SDS Number	30
Product use	Professional use

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Use of the substance/mixture Auxiliary for manufacture of dental prosthesis
For medical use

Uses advised against No additional information available.

1.3. Details of the supplier of the safety data sheet

Supplier

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Deutschland
Tel.: + 49 6251 16-0
Fax: + 49 6251 16-2591
Internet: www.sirona.com
E-Mail: contact@sirona.com

1.4. Emergency telephone number

+ 49 (0) 6131 19240
GIZ (Poison Center) Mainz

2. SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008

Physical hazards	Aerosol, Category 2	H223;H229	Flammable aerosol. Pressurised container: May burst if heated.
Health hazards	Specific target organ toxicity — Single exposure, Category 3, Narcosis	H336	May cause drowsiness or dizziness.
Environmental hazards	Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412	Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008

Hazard pictograms



Signal word

Warning

Contains	Pentane
Hazard statements	
H223	Flammable aerosol.
H229	Pressurised container: May burst if heated.
H336	May cause drowsiness or dizziness.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements	
Prevention	
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211	Do not spray on an open flame or other ignition source.
P251	Do not pierce or burn, even after use.
P261	Avoid breathing vapours, spray, mist.
Response	
P312	Call a doctor, a POISON CENTER if you feel unwell.
Storage	
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50 °C.
Supplemental hazard information	
EUH066	Repeated exposure may cause skin dryness or cracking
Extra phrases	For professional users only.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

3. SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical name	CAS- No EC- No Index No RRN	%	Classification according to Regulation (EC) No. 1272/2008	Notes
1,1,1,2,3,3,3- heptafluoropropane	431-89-0 207-079-2 01-2119485489-18- XXXX	85 - < 90	Press. Gas (Diss.), H280	
Pentane	109-66-0 203-692-4 601-006-00-1 01-2119457435-35- XXXX	1 - < 10	Flam. Liq. 1, H224 STOT SE 3, H336 Asp. Tox. 1, H304 Aquatic Chronic 2, H411	# (Note C)

Note C : Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In this case the supplier must state on the label whether the substance is a specific isomer or a mixture of isomers.

#: substance with a Community workplace exposure limit

Full text of H-statements: see section 16

4. SECTION 4: First aid measures

4.1. Description of first aid measures

General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Inhalation:	Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

Skin contact:	Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eyes contact	Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.
Ingestion	Immediately call a POISON CENTER/doctor. Do not induce vomiting. Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects: May cause drowsiness or dizziness.

4.3. Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

5. SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Water spray. Dry powder.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard Extremely flammable aerosol.

Explosion hazard Pressurised container: May burst if heated.

Reactivity in case of fire During fire, gases hazardous to health may be formed.

Hazardous combustion products Carbon dioxide. Carbon monoxide. Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers.

Protection during firefighting Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Wear fire/flame resistant/retardant clothing.

Other information Use standard firefighting procedures and consider the hazards of other involved materials.

6. SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures Do not handle until all safety precautions have been read and understood. Eliminate every possible source of ignition.

For non-emergency personnel

Protective equipment Use personal protective equipment as required. Wear appropriate protective equipment and clothing during clean-up.

Emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

For emergency responders

Protective equipment Wear recommended personal protective equipment.

Emergency procedures Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

6.2. Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Remove all sources of ignition. Keep away from combustible material. Stop the leak.

Other information Prevent entry into waterways, sewer, basements or confined areas.

6.4. Reference to other sections For further information refer to section 8: "Exposure controls/personal protection". For further information refer to section 13.

7. SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling Keep away from sources of ignition - No smoking. Do not pierce or burn, even after use. Use only outdoors or in a well-ventilated area. Ground/bond container and receiving equipment. Avoid prolonged exposure. Avoid contact with eyes. Observe good industrial hygiene practices. Do not eat, drink or smoke when using this product. Wear appropriate personal protective equipment. Keep only in original container. Avoid release to the environment.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F. Store locked up. Store in a well-ventilated place. Keep container tightly closed. Keep away from ignition sources.

7.3. Specific end use(s) For medical use.

8. SECTION 8: Exposure controls/personal protection

8.1. Control parameters

EU

Regulation	Substance	Type	Value
COMMISSION DIRECTIVE 2006/15/EC	Pentane (109-66-0) Pentane	IOELV TWA IOELV TWA	3000 mg/m ³ 1000 ppm

United Kingdom

Regulation	Substance	Type	Value
EH40. HSE	Pentane (109-66-0) Pentane	WEL TWA WEL TWA	1800 mg/m ³ 600 ppm

DNEL: Derived no effect level

No data available

Components	Type	Route	Value	Form
Pentane (109-66-0)	Worker	Dermal	432 mg/kg bodyweight/day	Long-term - systemic effects
		Inhalation:	3000 mg/m ³	Long-term - systemic effects
	Consumer	Oral	214 mg/kg bodyweight/day	Long-term - systemic effects
		Inhalation:	643 mg/m ³	Long-term - systemic effects
		Dermal	214 mg/kg bodyweight/day	Long-term - systemic effects

PNEC: Predicted no effect concentration

No data available

Components	Type	Route	Value	Form
Pentane (109-66-0)	Not applicable	Freshwater	230 µg/L	
		Seawater	230 µg/L	

Freshwater	880 µg/L	Intermittent release
sediment	1.2 mg/kg dwt	Freshwater
sediment	1.2 mg/kg dwt	Seawater
Soil	0.55 mg/kg dwt	
STP	3600 µg/L	

8.2. Exposure controls

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level		
Materials for protective clothing	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment		
Individual protection measures, such as personal protective equipment (PPE)			
Eye protection	If contact is likely, safety glasses with side shields are recommended.		
Skin protection			
Hand protection	Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls		
Other protective measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.		
Respiratory protection	In case of inadequate ventilation wear respiratory protection.		
Device	Filter type	Condition	Comments
	Type AX - Low-boiling (<65 °C) organic compounds, Type P2		
Thermal hazard protection	Wear appropriate thermal protective clothing, when necessary.		
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases.		

9. SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aerosol.
Colour	light blue.
Odour	Characteristic.
Odour threshold	No data available
pH	No data available
Relative evaporation rate (butylacetate=1)	No data available
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	-40 °C (calculated value)
Auto-ignition temperature	260 °C
Decomposition temperature	No data available
Flammability (solid, gas)	Extremely flammable aerosol
Vapour pressure	3000 - 4000 hPa
Relative vapour density at 20 °C	No data available
Relative density	No data available
Density	1.3 g/ml
Solubility	No data available
Log Pow	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available

Explosive properties	May form explosive/flammable vapor/air mixtures during use.
Oxidising properties	None.
Lower explosive limit (LEL)	1.4 vol %
Upper explosive limit (UEL)	8 vol %

9.2. Other information

No additional information available.

10. SECTION 10: Stability and reactivity

10.1. Reactivity	Extremely flammable aerosol. Pressurised container: May burst if heated.
10.2. Chemical stability	Stable under normal conditions of use.
10.3. Possibility of hazardous reactions	No dangerous reactions known under normal conditions of use.
10.4. Conditions to avoid	Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.
10.5. Incompatible materials	No additional information available.
10.6. Hazardous decomposition products	Carbon monoxide. Carbon dioxide. Various hydrocarbon fragments.

11. SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Additional information	Repeated exposure may cause skin dryness or cracking
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
STOT-single exposure	May cause drowsiness or dizziness.
STOT-repeated exposure	Not classified
Aspiration hazard	Not classified
Potential adverse human health effects and symptoms	Occupational exposure to the substance or mixture may cause adverse effects.

12. SECTION 12: Ecological information

12.1. Toxicity

Ecology - general Harmful to aquatic life with long lasting effects.

Acute aquatic toxicity

Substance / Product	Trophic level	Species	Type	Value	Duration	Remarks
1,1,1,2,3,3,3-heptafluoropropane (431-89-0)	crustacea		EC50	>200 mg/l	48h	
	algae		ErC50	>114 mg/l	72h	
Pentane (109-66-0)	Fish		LL50	27,55 mg/l	96h	

12.2. Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

1,1,1,2,3,3,3-heptafluoropropane (431-89-0)

Log Kow	2.289
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Pentane (109-66-0)

Bioconcentration factor (BCF REACH)	171
Log Kow	3.45

12.4. Mobility in soil

No additional information available.

12.5. Results of PBT and vPvB assessment

Cerec Optispray 200ml

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

12.6. Other adverse effects

Other adverse effects This product contains a fluorinated greenhouse gas.

13. SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Waste treatment methods	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
Additional information	Dispose in accordance with all applicable regulations.
European List of Waste (LoW) code	
16 05 04*	gases in pressure containers (including halons) containing dangerous substances

14. SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	1950
UN-No. (IMDG)	1950
UN-No. (IATA)	1950
UN-No. (ADN)	1950
UN-No. (RID)	1950

14.2. UN proper shipping name

Proper Shipping Name (ADR)	AEROSOLS
Proper Shipping Name (IMDG)	AEROSOLS
Proper Shipping Name (IATA)	Aerosols, flammable
Proper Shipping Name (ADN)	AEROSOLS
Proper Shipping Name (RID)	AEROSOLS

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	2.1
Danger labels (ADR)	2.1

IMDG

Transport hazard class(es) (IMDG)	2.1
Danger labels (IMDG)	2.1

IATA

Transport hazard class(es) (IATA)	2.1
Hazard labels (IATA)	2.1

ADN

Transport hazard class(es) (ADN)	2.1
Danger labels (ADN)	2.1

RID

Transport hazard class(es) (RID)	2.1
Danger labels (RID)	2.1

14.4. Packing group

Packing group (ADR)	Not applicable
Packing group (IMDG)	Not applicable
Packing group (IATA)	Not applicable
Packing group (ADN)	Not applicable
Packing group (RID)	Not applicable

14.5. Environmental hazards

Dangerous for the environment	No
Marine pollutant	No
Other information	No supplementary information available.

14.6. Special precautions for user

Overland transport

Classification code (ADR)	5F
Special provisions (ADR)	190, 327, 344, 625
Limited quantities (ADR)	1I
Packing instructions (ADR)	P207, LP02
Tunnel restriction code (ADR)	D

Transport by sea

Special provisions (IMDG)	63, 190, 277, 327, 344, 959
Limited quantities (IMDG)	SP277
Packing instructions (IMDG)	P207, LP02
EmS-No. (Fire)	F-D
EmS-No. (Spillage)	S-U
Stowage category (IMDG)	None

Air transport

PCA Excepted quantities (IATA)	E0
PCA Limited quantities (IATA)	Y203

PCA limited quantity max net quantity (IATA)	30kgG
PCA packing instructions (IATA)	203
PCA max net quantity (IATA)	75kg
CAO packing instructions (IATA)	203
CAO max net quantity (IATA)	150kg
Special provisions (IATA)	A145, A167, A802
ERG code (IATA)	10L

Inland waterway transport

Classification code (ADN)	5F
Special provisions (ADN)	190, 327, 344, 625
Limited quantities (ADN)	1 L

Rail transport

Classification code (RID)	5F
Special provisions (RID)	190, 327, 344, 625
Limited quantities (RID)	1L
Packing instructions (RID)	P207, LP02
Hazard identification number (RID)	23

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

15. SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006

Pentane	3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008
Pentane	3(a) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F
Pentane	3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
Pentane	3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1
Pentane	40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Other information, restriction and prohibition regulations

Directive 94/33/EC on the protection of young people at work, as amended. 1,1,1,2,3,3,3-Heptafluoropropane (R-227ea), CAS No : 431-89-0 is exempted from the prohibition of mixtures containing fluorinated greenhouse gases in accordance with REGULATION (EU) No 517/2014 as it is used for medical applications. For details, refer to section 3 and 8.

Seveso Information

P3a

National regulations

No additional information available.

15.2. Chemical safety assessment

No additional information available.

16. SECTION 16: Other information

Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road.
ATE	Acute Toxicity Estimate.
BCF	Bioconcentration factor.
CAO	Cargo Aircraft Only.
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
DNEL	Derived-No Effect Level.
IATA	International Air Transport Association.
IMDG	International Maritime Dangerous Goods.
OEL	Occupational Exposure Limit.
PBT	Persistent Bioaccumulative Toxic.
PCA	Passenger and Cargo Aircraft.
PNEC	Predicted No-Effect Concentration.
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail.
RRN	REACH Registration no..
SDS	Safety Data Sheet.
STP	Sewage treatment plant.
TLM	Median Tolerance Limit.
TWA	Time Weighted Average. The average concentration of a chemical in air over the total exposure time-usually an 8-hour workday..
VOC	Volatile organic compounds.
vPvB	Very Persistent and Very Bioaccumulative.

Data sources

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006..

Training advice

Normal use of this product shall imply use in accordance with the instructions on the packaging

Full text of H- and EUH-statements

Aerosol 2	Aerosol, Category 2.
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2.
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3.
Asp. Tox. 1	Aspiration hazard, Category 1.
Flam. Liq. 1	Flammable liquids, Category 1.
Press. Gas (Diss.)	Gases under pressure : Dissolved gas.
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis.
H223	Flammable aerosol.
H224	Extremely flammable liquid and vapour.

H229	Pressurised container: May burst if heated.
H280	Contains gas under pressure; may explode if heated.
H304	May be fatal if swallowed and enters airways.
H336	May cause drowsiness or dizziness.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH066	Repeated exposure may cause skin dryness or cracking.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Aerosol 2	H223;H229	On basis of test data
STOT SE 3	H336	Practical experience
Aquatic Chronic 3	H412	Calculation method

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.